REMARKS/ARGUMENTS

Claims 49-87 are currently pending in the instant application. The present Office Action includes rejections under 35 U.S.C. §102 and §103, responses to which are discussed below.

Claims 49-87 have been canceled without prejudice and Applicants reserve their right to prosecute the subject matter of these claims in one or more continuation, continuation-in-part, or divisional applications.

New claims 88-98 have been added.

Support for new claim 88 can be found on page 5, lines 17-20. New claims 89-90 are essentially previous claims 63-64, respectively, with the addition of the phrase "relative to the same amount of modafinil in a solid oral dosage form." Support for these amendments can be found in Example 3 on page 17 of the application and in original claims 35 and 38. These claims have been amended to more particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. No new subject matter has been added.

Support for new claim 91 can be found on page 5, lines 24-27, in Example 3 on page 17-18, and in Figure 1.

New claim 92 is related to previous claim 71, with a change in the claim dependency to new claims 88, 89, or 90. Support for this amendment can be found in Example 3 on page 17 of the application and in original claim 48. This claim has been amended to more particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. No new subject matter has been added.

New claims 93-98 have been added. Support for claim 93 can be found on page 17, lines 12-15. Support for claim 94 can be found on page 4, lines 22-23. Support for claim 95 can be found on page 1, lines 26-29. Support for claims 96-98 can be found on page 12, lines 29-32. These claims have been amended to more particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. No new subject matter has been added.

I. Rejection Under 35 U.S.C. § 102(b)

Claims 49, 51, 52, 54, 57-59, 63-67, 71-73, 77, 78 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Rambert et al with Hedges to support inherency as

applied to canceled claims 1-5, 9, 10, 12-19, 21, 24, 25, 28, 35-43, 46 and 48 in the previous office action.

Applicants have canceled claims 49, 51, 52, 54, 57-59, 65-67, 72-73, 77, 78 and 81, thereby rendering the rejection moot with respect to those claims.

The Examiner maintains the rejection for new claims 89-90 and 92, which correspond to old claims 63, 64 and 71, respectively, for reasons set forth in the first Office Action, dated May 6, 2003. With respect to claims 89 and 90 (old claims 63 and 64), the Examiner alleged that the claims "are written broadly with no requirement regarding the amount of composition to be administered in order to produce recited profile [*sic*]. A dose of RAMBERT composition comprising 200 μg of modafinil would provide the recited blood serum level increases over a dose of 100 μg of modafinil." (Office Action dated May 6, 2003, pp. 4-5).

Applicants respectfully submit that contrary to the Examiner's assertion that all elements of the current invention are disclosed by the references, the element that requires "at least a 25% increase in the blood serum level of a modafinil compound in a mammal upon oral administration relative to the same amount of modafinil in a solid oral dosage form" is not, so the rejection is unsupported by the art. Indeed, the example stated in the rejection does not read upon the claims. Hence, Applicants respectfully submit that the references neither disclose, nor suggest the current invention.

With respect to new claim 92, which corresponds to old claim 71, the Examiner alleged that the administration of some amount of the RAMBERT composition would produce the blood serum profile of Figure 1. Applicants respectfully submit that contrary to the examiner's assertion that all elements of the current invention are disclosed by the references, the element that requires the blood serum level of Figure 1 upon oral administration is not, so the rejection is unsupported by the art. The Examiner's assertion that the RAMBERT composition "would" produce the same profile is unsubstantiated. The fact remains that the references made no such teaching. The references fail to teach any blood serum profile, nor do they teach oral administration of a modafinil/cyclodextrin composition. Hence, Applicants respectfully submit that the references neither disclose, nor suggest the current invention.

In view of the above amendments and remarks, reconsideration and withdrawal of the rejection under §102 is respectfully requested.

II. First Rejection Under 35 U.S.C. § 103(a)

Claims 49-52, 54-67, 70-73, 77, 78, 81 and 83 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rambert et al. in view of Pitha et al. as applied to canceled claims 1-10, 12-19, 21-24, 28, 35-43 and 46-48 in the previous office action.

Applicants have canceled claims 49-52, 54-62, 65-67, 70, 72-73, 77, 78, 81 and 83 thereby rendering the rejection moot with respect to those claims.

The Examiner maintains the rejection for new claims 89-90 and 92, which correspond to old claims 63, 64 and 71, respectively, for reasons set forth in the first Office Action, dated May 6, 2003. The Examiner alleged the RAMBERT teachings as outlined above, and that PITHA teaches that 2-HP-β-cylclodextrin is useful for solubilizing drugs with limited water solubility.

Applicants respectfully submit that the references, either alone, or in combination, do not teach the claimed invention. New claims 89 and 90 involve compositions that provide at least a 25% and a 50% increase in the blood serum level of a modafinil compound in a mammal upon oral administration relative to the same amount of modafinil in a solid oral dosage form. Claim 92 involves compositions that give the blood serum profile as outlined in Figure 1. As discussed above, RAMBERT fails to teach these limitations, and as such, it fails to teach the disclosure of the instant application, and therefore the instant claims are non-obvious.

Applicants respectfully submit that PITHA does not cure the deficiencies of RAMBERT, and that the instant claims are non-obvious over RAMBERT in light of PITHA. PITHA teaches use of cyclodextrins for solubilizing drugs with limited water solubility. PITHA fails to teach any blood serum profiles, let alone the blood serum profile of the instant compositions, nor does it teach the increase in blood serum levels with compositions of the present invention. Hence, the claims of the current application have not been taught nor suggested by the prior art, alone or in combination, and as such are non-obvious.

In view of the above amendments and remarks, reconsideration and withdrawal of the rejection under §103 is respectfully requested.

III. Second Rejection Under 35 U.S.C. § 103(a)

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rambert et al. (Neuropharmacology, 1994) as applied to claims 49, 51, 52, 54, 57-59, 63-67, 69-73, 77, 78, 81, and 83 above, further in view of Nguyen et al. (US 5,843,347) and Hedges (Chem. Rev., 1998).

Applicants have canceled claim 84 thereby rendering the rejection moot with respect to that claim. Hence, Applicants respectfully request withdrawal of the rejection.

IV. Third Rejection Under 35 U.S.C. § 103(a)

Claims 53, 68, 74-76, 79, 80, 82, and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rambert et al. (Neuropharmacology, 1994) in view of Nguyen et al. (US 5,843,347) and Hedges (Chem. Rev., 1998) as applied to claims 49, 51, 52, 54, 57-59, 63-67, 69-73, 77, 78, 81, 83, and 84 above, and further in view of GREBOW et al. (US 5,618,845).

Applicants have canceled claims 53, 68, 74-76, 79, 80, 82, and 85-87 thereby rendering the rejection moot with respect to those claims. Hence, Applicants respectfully request withdrawal of the rejection.

V. Fourth Rejection Under 35 U.S.C. § 103(a)

Claims 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of (1) Lafon (US 5,391,576); (2) Scammell et al. (US 6,455,588); or (3) Miller et al. (US 6,346,548), as applied to canceled claims 32-34 in the previous Office action.

Applicants have canceled claims 85-87 thereby rendering the rejection moot with respect to those claims. Hence, Applicants respectfully request withdrawal of the rejection.

VI. Conclusion

Entry of the remarks and amendments and reconsideration of the present application is respectfully requested. In view of the above, it is believed that all the claims are in form for allowance, and an early notification to that end is respectfully requested.

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